



**FDA Requirement: Prescriber Certification Needed to Prescribe Tikosyn and its Authorized Generic**

[Date]

Dear Dr. [insert last name]:

**Per the Food and Drug Administration (FDA) requirements, in order to prescribe TIKOSYN or its authorized generic, new prescribers are required to complete a one-time certification.** TIKOSYN and its authorized generic are indicated for the conversion to and maintenance of normal sinus rhythm (delay in the time to recurrence of atrial fibrillation/atrial flutter) in highly symptomatic patients with atrial fibrillation/atrial flutter of greater than 1 week.

The TIKOSYN and Authorized Generic Education Distribution Program, currently known as the TIKOSYN and Authorized Generic Risk Evaluation and Mitigation Strategy (REMS), is required by the FDA to ensure safe use of TIKOSYN and its authorized generic in order to mitigate the risk of induced arrhythmia by:

- Ensuring that TIKOSYN and its authorized generic are prescribed only by certified prescribers, and dispensed only by certified dispensers;
- Educating health care providers about the risks and the need to initiate and re-initiate therapy in a health care facility that can provide calculations of creatinine clearance, continuous electrocardiographic monitoring, and cardiac resuscitation;
- Informing patients about the serious risks associated with TIKOSYN and its authorized generic therapy.

In order to become certified, you must review the enclosed materials and sign the certification form. The materials include the following:

- TIKOSYN and Authorized Generic Treatment Guidelines
- Prescribing Information
- Medication Guide
- Tikosyn and Authorized Generic Prescriber Certification Form

When you have reviewed all the materials, **please sign and mail or fax back the certification form.** The fax number is (800)-788-2637. After we have received your certification form, we will send a written confirmation of receipt.

In addition to your certification, **retail pharmacies** and **institutional pharmacies** must also be certified in order to dispense TIKOSYN and its authorized generic. Before dispensing a prescription for TIKOSYN or its authorized generic, the pharmacist must confirm that you



U.S. Pharmaceuticals  
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New York, NY 10017-5755

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are a health care professional who has been certified and is listed in the Pfizer National TIKOSYN and Authorized Generic Database.

It is important that you tell your patients to fill their TIKOSYN or its authorized generic prescriptions as soon as possible after they are discharged to avoid any disruptions in their treatment. Although patients must be provided with TIKOSYN or its authorized generic upon discharge, it may take a few business days for the pharmacy to order TIKOSYN or its authorized generic for subsequent prescriptions.

Should you have any questions regarding the certification program, please call 1-866-249-7261 or visit [www.TIKOSYNREMS.com](http://www.TIKOSYNREMS.com).

Regards,

A handwritten signature in blue ink that reads "Pol Vandenbroucke".

Pol Vandenbroucke, MD, MSc, MBA, FFPM  
Regional Medical Affairs Lead, North America  
Global Established Pharma, Pfizer Inc.